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Understanding the Rules and Responsibilities

by Elizabeth Wager

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Medical Writers and Peer-Reviewed Journals

By Elizabeth Wager

Executive summary

Medical writers perform an invaluable role in the dissemination of scientific information, in particular the publication of clinical trial results. However, their work has not always been acknowledged. The pharmaceutical industry has endured much criticism of how it reports clinical trials. High-profile abuses of publication ethics from within the industry have fuelled suspicions of the sector and, by association, damaged the reputations of responsible writers and communications companies. This has led to escalating calls for greater transparency in the relationships between journals, medical writers and pharmaceutical sponsors. Many journals have responded by establishing and enforcing stricter guidelines on the publication of clinical trials.

Editors and readers have responded to concerns about conflicts of interest in publications by demanding greater information on individuals involved in developing publications. Policies of disclosing individuals' contributions to publications have increased awareness of the roles of company employees previously hidden from public view and brought about wider acknowledgement of the work of medical writers.

This Expert Review, *Medical Writers and Peer-Reviewed Journals: Understanding the Rules and Responsibilities*, looks at the complexities of reporting clinical trials and the important role played by medical writers. It outlines guidelines affecting medical writers that are being adopted by many journals and medical editor associations. It calls on journals and sponsor companies to work together to embrace transparency and to agree best practice in the publication of clinical trials.

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Introduction

Coordinating and publishing clinical trials is a multimillion-dollar global market involving international companies and huge numbers of people. Peer-reviewed journals are an indispensable part of the process. However, many journals are only now becoming aware of the complexities of pharmaceutical research, with published guidelines and some journal conventions failing to reflect the real world.

Healthcare companies deploy thousands of medical writers to work on publications but, until recently, their roles were poorly defined and often misunderstood outside the industry. Indeed, some journal editors and academics viewed professional writers with suspicion or outright hostility. However, in the past 5 years, several guidelines and policy statements relating to medical writers have been published. Professional writers have subsequently gained greater recognition among medical journals and been catapulted from obscurity into a strange new world that demands transparency and the consideration of multiple guidelines. This Expert Review, *Medical Writers and Peer-Reviewed Journals: Understanding the Rules and Responsibilities*, explains the concerns about the role of medical writers in developing peer-reviewed publications and will help writers and communications companies keep abreast of recent guidelines and new journal policies.

Liz Wager
June 2007

About the author

Elizabeth (Liz) Wager is the author of books on '*Getting Research Published: An A to Z of Publication Strategy*' and '*How to Survive Peer Review*'. She is a co-author of '*Good Publication Practice for Pharmaceutical Companies*' and the European Medical Writers Association guidelines on the role of medical writers.

After obtaining a First Class zoology degree from Oxford in 1983 she worked for Blackwell Scientific Publications, Janssen-Cilag then Glaxo-Wellcome. In 2001, she set up her own company, Sideview, which provides training, writing, editing and publication consultancy services.

She is a member of: the *BMJ*'s Ethics Committee, the World Association of Medical Editors Ethics Committee, the Council of the Committee on Publication Ethics, the editorial board of *European Science Editing* (the journal of the European Association of Science Editors) and the World Health Organization Scientific Advisory Group on trial registration.

She can be contacted at: liz@sideview.demon.co.uk or via www.lizwager.com

Medical Writers and Peer-Reviewed Journals

What's the problem?

Large-scale randomized trials are a vital component of evidence-based medicine and modern healthcare, and represent major investments for the pharmaceutical industry. Given their significance, it is easy to overlook the fact that such trials are fairly recent phenomena, dating back only to the late 1940s.[1] In just under 60 years the discipline of clinical trial methodology has developed and, more recently, a new industry of clinical trial management has also emerged. Furthermore, the complexity of clinical trials has increased in the past 40 years, and this has been mirrored by a steady growth in the average number of authors per research paper (Figure 1).[2,3] Most recently, in Europe at least, the European Union Clinical Trials Directive has greatly increased the bureaucratic requirements imposed on trialists, further hastening the demise of the single-centre, sole-investigator study and necessitating a greater professionalism in clinical trial management.

The complexity of clinical trials has increased in the past 40 years, and this has been mirrored by a steady growth in the average number of authors per research paper

Many journals originated over 100 years ago, and the peer-review process began over two centuries ago,[4] so it is perhaps unsurprising that reactions to the rapid development of industry-sponsored trials have been diverse, with some editors and institutions embracing change more willingly than others. The industry itself should also take its share of the blame for the confusion, since, until recently, many companies did little to dispel the misconceptions about how trials are usually conducted and published.[5] Company authorship policies actually perpetuated the myth of a handful

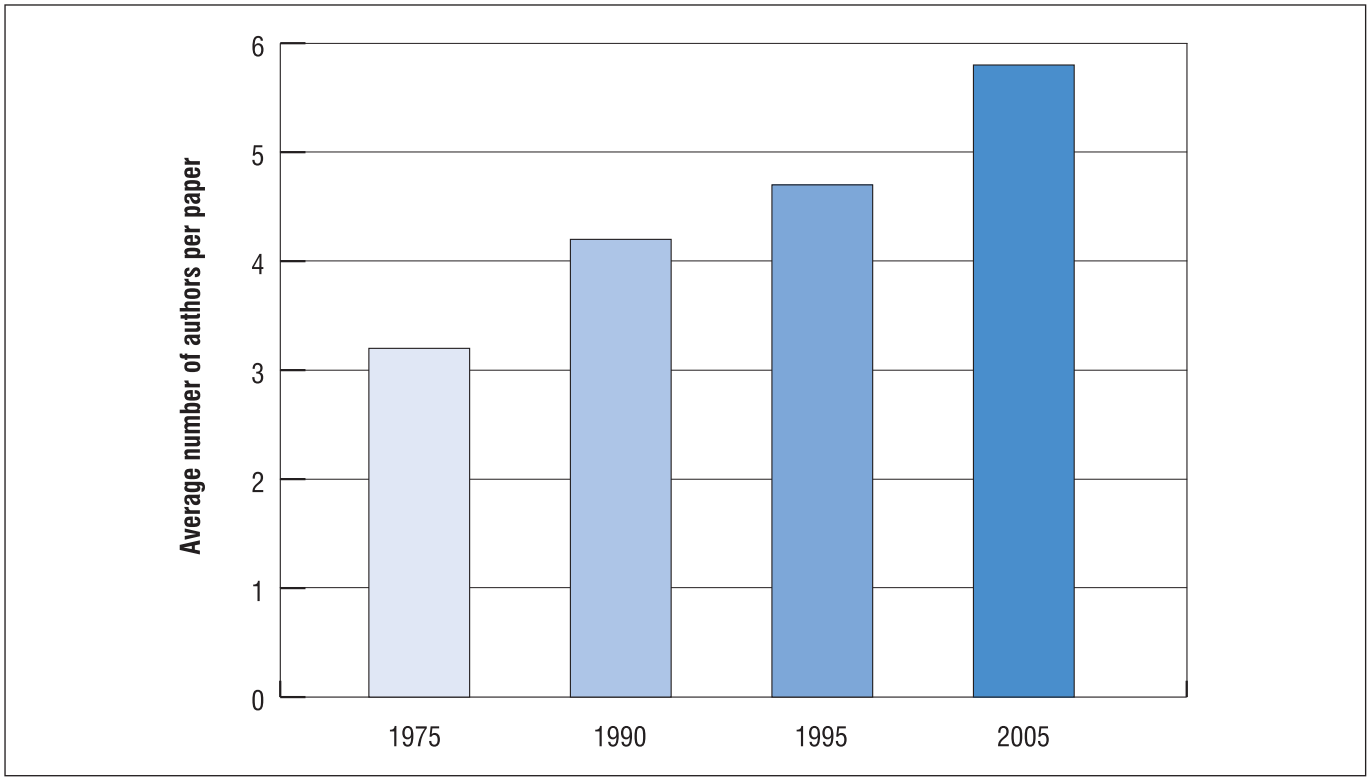

Fig. 1. Average number of authors per paper in major medical journals. Data from Levsky et al.[2] and Drenth.[3]

of independent investigators designing, conducting, analysing and reporting trials with virtually no input from the sponsor (except, presumably, a healthy injection of cash) since company personnel were rarely acknowledged. In the process, journal editors and readers became accustomed to papers reporting industry-sponsored studies that listed as authors only the key academic investigators. These editors, quite understandably, assumed that the named authors were solely responsible for the study design and analysis, and also concluded that they would have written the paper themselves. The roles of doctors, statisticians and writers working in or for the sponsoring companies were rarely mentioned, and therefore, outside the industry, the misconception spread.

Journal editors and academics are gradually realising that the picture is nowhere near as simple as they once thought. Commercial sponsors are actively involved in all stages of clinical trial design, analysis and reporting, working in close collaboration with external investigators, but nevertheless making crucial intellectual contributions. This revelation appeared to come as a heavy blow to some editors, who railed against the corruption of academic medicine and proposed Draconian measures to restore the purity of the process.[6] One could even draw parallels with the stages of bereavement as editors moved from denial, to anger and gradually to acceptance. The editors have lost a cosy (and distinctly rose-tinted) image of the way in which clinical trials are carried out and are taking time to adjust to the new, more complex, realities.

Some editors have railed against the corruption of academic medicine and proposed Draconian measures to restore the purity of the process

But it would be churlish to suggest that editors' concerns about the way in which trials get reported and drug companies manage their publication strategies were solely a product of their own misconceptions. Some companies and individuals have behaved irresponsibly. There have been some high-profile abuses of publication ethics from within the industry, including well-documented cases of companies attempting to suppress unfavourable findings, and instances where investigator–sponsor relations have not always been respectful. For example, companies have sometimes submitted abstracts or manuscripts without consulting or even informing the named authors, and occasionally opinion leaders have been asked to add their names to articles to which they have made no contribution.[7,8] Anecdotal evidence of such bad practice has, understandably, fuelled suspicion about industry practices, whereas the many responsible companies and good writers, keen to ensure high-quality publications, are rarely mentioned.

Who's bothered – and why should we be bothered?

Journal editors have become increasingly concerned about undisclosed conflicts of interest and a lack of transparency in publications. Having realised that healthcare manufacturers are closely involved with all stages of conducting and reporting clinical trials, many journals now require descriptions of this involvement. The general media has also picked up on stories of undisclosed commercial involvement and, as a consequence, pharmaceutical and communications companies have suffered public criticism of their behaviour and publication practices. To avoid such censure, professional writers and publication planners should advise clients about journal and meeting requirements, and warn them about the possible consequences if they breach guidelines. Journals have been known to blacklist authors found guilty of multiple submissions of the same paper at one time to different journals and can retract redundant publications. Policies of disclosing individuals' contributions to publications, rather than just listing authors' names and affiliations, have increased awareness of the roles of company employees such as statisticians and writers.

Professional writers and publication planners should advise clients about journal and meeting requirements, and warn them about the possible consequences if they breach guidelines

In addition, a number of organisations have issued guidelines or policy statements aimed at drug companies, medical writers, authors or journal editors offering guidance in this area (Table 1).

The great authorship debate

Many of the concerns about professional writers working on peer-reviewed publications revolve around authorship. The ICMJE (International Committee of Medical Journal Editors) criteria for determining authorship are the most widely followed and have been endorsed by many journals (Figure 2). However, some editors have highlighted the shortcomings of these guidelines[9] and several studies have shown that they are not universally known or respected among researchers.[10,11]

Based on the ICMJE criteria, medical writers who are involved only in the final stages of manuscript development, and who have not been involved with data

	Full name	Title	Main audience	Published/ updated	Source
GPP	Good Publication Practice	Guidelines for pharmaceutical companies	Drug companies	2003	www.gpp-guidelines.org
PhRMA	Pharmaceutical Research and Manufacturers of America	Principles on communication of clinical trial results	Drug companies	2002	www.phrma.org
EMWA	European Medical Writers Association	Role of medical writers in developing peer-reviewed publications	Medical writers	2005	www.emwa.org
ICMJE	International Committee of Medical Journal Editors	Uniform requirements for submission of manuscripts to biomedical journals	Authors	2003	www.icmje.org
WAME	World Association of Medical Editors	Policy statements: ghost writing/authorship	Journal editors	2005/2007	www.wame.org
CSE	Council of Science Editors	Policy statement: promoting integrity of scientific journals	Journal editors	2006	www.councilscienceeditors.org

Table 1. Key guidelines and policy statements.

analysis or interpretation, do not qualify to be listed as authors of papers reporting clinical trials. Some editors argue that the act of preparing a draft involves sufficient interpretation to qualify for authorship – but they are in a small minority.

Perhaps the most helpful clause of the ICMJE guidelines for deciding whether somebody should be included in the author list is the statement that authors must be able to take public responsibility for the work. Most people interpret this to mean that only those who would be prepared to stand up in public, defend the study design and present the findings should be included as authors. An academic once told me he applied the 'flying to Rio test': imagine the senior author dies suddenly, the day before he is due to fly to Rio de Janeiro to present the study – only people who could step in and make the presentation should be included as authors. Similarly, WAME (the World Association of Medical Editors) states that '*Only an individual who has made substantial intellectual contributions should be an author*'.

Most professional writers, while happy to take responsibility for the way in which a trial is reported, could not take responsibility for the design or conduct of the study, and would not be qualified to offer a clinical interpretation. For these reasons, the EMWA (European Medical Writers Association) guidelines on the role of medical writers in developing peer-reviewed publications state that '*in most publications reporting clinical trials, a medical writer who has not been involved in study design, data analysis, or interpretation will not qualify to be listed as an author*'.

However, the situation for other types of publication is often less clear. For example, if a professional writer has performed a literature review, determined which studies to include, prepared tabulations of the findings

Authorship credit should be based on:

1) substantial contributions to conception and design, or acquisition of data, or analysis and interpretation of data;
2) drafting the article or revising it critically for important intellectual content; and
3) final approval of the version to be published.

Authors should meet conditions 1, 2, and 3.

- Acquisition of funding, collection of data, or general supervision of the research group, alone, does not justify authorship.
- All persons designated as authors should qualify for authorship, and all those who qualify should be listed.
- Each author should have participated sufficiently in the work to take public responsibility for appropriate portions of the content.
- All contributors who do not meet the criteria for authorship should be listed in an acknowledgments section. Examples of those who might be acknowledged include a person who provided purely technical help, writing assistance, or a department chair who provided only general support. Financial and material support should also be acknowledged.

Fig. 2. ICMJE authorship criteria.

and produced the first draft of a review article, many would argue that they would qualify for authorship just as much, if not more, than somebody who provides critical review and clinical interpretation of the data. The EMWA guidelines therefore go on to state that medical writers '*may qualify for authorship of review articles, for example, if they have conducted an extensive literature search*'.

> 'In most publications reporting clinical trials, a medical writer who has not been involved in study design, data analysis, or interpretation will not qualify to be listed as an author'
>
> EMWA guidelines

The guidelines on Good Publication Practice (GPP) for pharmaceutical companies do not provide such detailed guidance on whether medical writers should be authors but do make the important point that, whatever criteria are used to determine authorship, they should be applied equally to company employees and external investigators. This recommendation was a reaction to policies restricting company authorship that existed in many pharmaceutical companies in the 1980s and '90s.[12] The introduction to the GPP guidelines makes it clear that they apply to anybody involved in developing publications, be they employees of the research sponsor, freelancers or people working in communications companies. The term 'employees' should therefore be interpreted in its widest sense to include anybody working for, or on behalf of, the sponsoring company.

> *Journal calls for increased transparency and demands to list all contributors may have the effect of bringing all writers into the open*

Whereas drug companies appear to be increasingly prepared to list employees as authors, writers working for communications companies or freelancers have, until recently, been less likely to be acknowledged. However, journal calls for increased transparency and demands to list all contributors may have the effect of bringing all writers into the open.

Ghost authors versus ghost writers

One problem in the debate about the role of medical writers has been confusion over terminology. A ghost author is anybody who meets authorship criteria but is not listed. A recent study showed that company statisticians often fall into this category.[13] Ghost writing is the stuff of celebrity autobiographies and should have no place in peer-reviewed journals. Professional writers cannot be accused of being ghost writers if their role is properly acknowledged. However, a professional writer is not necessarily a ghost author since, as we have seen, they usually do not meet the criteria to be listed as authors.

> *Professional writers cannot be accused of being ghost writers if their role is properly acknowledged*

WAME has stated that: '*Ghost authorship exists when someone has made substantial contributions to writing a manuscript and this role is not mentioned in the manuscript itself. WAME considers ghost authorship dishonest and unacceptable*.'

Authors versus contributors

Some journals have responded to the authorship abuse that created ghost authors by requiring (and in many cases publishing) details about each individual's contribution to a publication and the research it reports. Rather than simply listing the authors' names and their affiliations, some journals now publish lists detailing who designed the study, analysed the data, wrote the first draft of the paper, etc. People listed in this way are termed 'contributors' rather than authors. This increased transparency has undoubtedly increased the visibility of company personnel (such as writers and statisticians working for the sponsor) who often, in the past, were unacknowledged ghosts.

Some journals' instructions make it clear that they expect all listed contributors to meet the ICMJE criteria. Others appear to have (tacitly or otherwise) abandoned the criteria but hope that the increased transparency of listing contributors will prevent guest and ghost authors. A few journals maintain a distinction between authors, whose names appear under the title, and contributors, whose names appear in a list, usually at the end of the paper. In such cases, in theory at least, it is possible to list a professional writer as a contributor (e.g. Jane Smith prepared the first draft) but not as an author. However, in practice, this rarely happens and most readers are probably unaware of the distinctions between authors and contributors.

Guarantors

One objection, voiced when contributorship was originally proposed, was that responsibility for a project and its publication would become fragmented. Each contributor could vouch for his or her own area of involvement or expertise, but nobody would be prepared

to take overall responsibility for the work. The ICMJE Uniform Requirements, and several journals that use the contributorship system, therefore require one of the contributors/authors to act as the guarantor who takes '*responsibility for the integrity of the work as a whole, from inception to published article*'.

Acknowledgements

Under the traditional system of authorship, people who had contributed to the study or paper in some way but who did not qualify to be authors could be listed in the acknowledgements section. This is where details of medical writing assistance usually appear. The ICMJE Uniform Requirements state that: '*All contributors who do not meet the criteria for authorship should be listed in an acknowledgments section. Examples of those who might be acknowledged include a person who provided purely technical help, writing assistance, or a department chair who provided only general support*.'

This guidance is echoed in the GPP guidelines, which state that: '*The Acknowledgments section of a paper should list those people who made a significant contribution to the study but do not qualify as authors. It should also be used to acknowledge the study's funding and the company's involvement in the analysis of the data or preparation of the publication unless this is apparent from the list of contributors/authors*.'

The EMWA guidelines also concur that writers should be acknowledged but go on to state that in some cases writers may wish to withdraw their names: '*Although EMWA encourages transparency about writers' involvement with publications, because it believes that this usually serves readers and reviewers best, it also acknowledges that writers retain the right to withdraw their names from publications in exceptional circumstances (just as researchers who qualify for authorship may sometimes withdraw their name from a paper if they disagree with the way in which the research is presented or interpreted). Such a situation might occur if the writer prepares an outline or initial draft which is so substantially altered or replaced by material from the named author that the writer no longer feels that acknowledgement is appropriate*.'

The EMWA guidelines also provide the most detail regarding exactly how medical writers should be acknowledged. In the past, acknowledgements often listed individuals without describing their role. Statements such as 'We thank Joan Brown for her help in preparing the manuscript' failed to distinguish whether this help took the form of typing the paper, checking references, preparing figures or a more substantive role. Such acknowledgements also failed to show whether the acknowledgees were employed or hired by the sponsor. The EMWA guidelines therefore encourage clarity: '*Vague acknowledgements of the medical writer's role, such as 'providing editorial assistance' should be avoided as they are open to a wide variety of interpretations. We suggest wording such as "We thank Dr Jane Doe who provided medical writing services on behalf of XYZ Pharmaceuticals Ltd*".'

> *The EMWA guidelines recommend acknowledgements to medical writers should take the form* "We thank Dr Jane Doe who provided medical writing services on behalf of XYZ Pharmaceuticals Ltd"

The instructions to authors from the *Journal of General Internal Medicine* warn that '*the precise financial relationships, direct and indirect, between parties involved [in contributing to a manuscript] must be explicitly described. Failing to do this will result in rejection of the manuscript*.'

Perhaps realising some journal editors' concerns, and in some cases paranoia, about the complexity of modern clinical trials, some companies (both sponsors and communications agencies) have resisted explicitly acknowledging the role of freelance or agency writers. Undoubtedly, some journal editors have seemed perplexed to discover that large-scale clinical trials often involve contract research organizations, and that publications are at times developed by medical communications companies. Yet the practice of not acknowledging freelance or agency writers cannot be justified when both journals and readers demand transparency and want to know precisely who did what. Such practices may lead to increased suspicion of the industry if the role of a freelance or agency writer is not disclosed in the initial submission but comes to light during the review process. Only a few journals recognise the problem explicitly. For example, the *Journal of General Internal Medicine* states, in its instructions, that: '*Anyone, including freelance writers and writers from communication and education companies, who contributes to reviewing the literature or drafting a manuscript must be listed as an author and complete a conflict of interest statement. Alternatively such persons can be listed in the Acknowledgements, including the conflict of interest information*.'

Whereas all the available guidelines emphasise the need to declare a writer's financial links with the sponsor, none of them provides guidance about whether agency names should be included. It is therefore up to the agency and its customer to agree whether it is best to write 'We thank Dr Jane Doe (of ABC Agency) who provided medical writing services on behalf of XYZ Pharmaceuticals Ltd' or to omit the agency's name. In cases where several writers have contributed to a manuscript, corporate acknowledgement might be most appropriate (e.g. 'ABC Agency provided medical writing assistance on behalf of XYZ Pharma Ltd') but it is not clear whether this would be acceptable to most journals.

For example, *The Lancet* instructions state: '*Was a medical writer or editor involved in the creation of your manuscript? If yes, we need a signed statement from the corresponding author to include the name and information on funding of this person. This information should be added to the Acknowledgment and/or Contributors section.' The Lancet* also requires *'a signed statement from this person declaring that he or she has given you permission to name him or her as an author, as a contributor, or in the Acknowledgment section*,' strongly suggesting that a corporate acknowledgement (without an individual writer's name) would not be acceptable.

What is clear, however, is that no matter how a medical writer is employed, their involvement and financial links to the sponsor must be recorded somewhere in manuscripts they have helped to develop. Whether they are listed as authors, or contributors, or in the acknowledgements section will depend on the nature of their involvement and the policies of the journal.

Opinion pieces, editorials and non-systematic reviews

The ICMJE authorship criteria apply primarily to research papers that report the results of clinical trials since they refer to activities such as designing studies and analysing data that do not apply in other types of publication. However, the ICMJE Uniform Requirements (and most journals) provide no explicit guidance about authorship of opinion pieces, editorials and non-systematic reviews.

The GPP guidelines suggest that '*While it is acceptable for professional writers or authors' editors to assist authors who have written editorials or opinion pieces (e.g., to improve the written style of authors whose first language is not English), it is not usually appropriate for them to prepare the first draft of such articles*.'

Some journals will not accept opinion pieces from authors with a clear financial interest in the topic. For example, *The Lancet* states: '*For Comment, Seminars, Reviews, and Series,* The Lancet *will decide not to publish if an author, within the past 3 years, and with a relevant company or competitor, has any stocks or shares, equity, a contract of employment, or a named position on a company board; or has been asked by any organisation other than* The Lancet *to write, be named on, or to submit the paper*.'

Some journals will not accept opinion pieces from authors with a clear financial interest in the topic

The New England Journal of Medicine (NEJM) states that '*Because the essence of reviews and editorials is selection and interpretation of the literature, the Journal expects that authors of such articles will not have any significant financial interest in a company (or its competitor) that makes a product discussed in the article*'. This policy was introduced in 2002, replacing a more stringent policy that authors of such articles should have no financial interest in the topic.[14] The journal's guidelines go on to explain that annual payments totalling more than $10,000 or substantial research funding are automatically considered 'significant' and therefore debar someone from authoring such an article. However, neither *The Lancet* nor *NEJM* mention anything about whether it is permissible for professional writers to be involved with such publications.

Other journals adopt a quite different policy designed to encourage transparency rather than prevent people with competing interests from publishing their opinions. The *BMJ* has recently extended its transparency and disclosure policy to include information about who suggested an article should be written and who commissioned it. The journal states '*For BMJ articles that do not report original research (such as editorials, clinical reviews, and education and debate) please state who had the idea for the article, who performed the literature search, who wrote the article, and who is the guarantor*'.

Gifts and guests

The other side of the authorship coin is the problem of individuals being listed as authors despite little or no involvement in the publication. Such people are known as guest or gift authors. Undeserving authors may be added as a favour, to increase the credibility of a publication or to increase its chance of acceptance. Gift authorship is not unique to industry-sponsored publications. In fact, it may be more common in academic circles where pressure to publish leads to mutual listing by colleagues (I'll put your name on my paper if you'll put my name on yours) or long-standing tradition means it is a career-limiting move not to include the department head on every paper. In one notorious

Professor Geoffrey Chamberlain resigned as editor of the *British Journal of Obstetrics and Gynaecology* after being named as a co-author of a paper that was later proved to be fraudulent. Professor Chamberlain is reported to have said that in hindsight he agreed that gift authorship was a bad idea but that he had "*rubber stamped this paper out of politeness and because he asked me to as head of the department*".

Fig. 3. The Chamberlain case.[15]

case, the editor of a well-known British journal was forced to resign after appearing as a guest author on a paper reporting research that turned out to be fraudulent (Figure 3).[15]

In both industry and academia, there have also been occasional instances when people have been named as authors on papers without their knowledge or permission. To counter this, some journals now require email addresses of all authors (not just the corresponding author) and send copies of correspondence to all authors so they are aware of the publication. For the same reasons, some journals will accept electronic submissions only from one of the named authors (and sometimes only the corresponding author), and do not permit other people to submit a manuscript on their behalf. Journals may also require all authors to sign an authorship declaration.

Medical writers can often be instrumental in ensuring that authors are properly involved and therefore do not fall into the category of guests or gifts. The EMWA guidelines suggest that writers should '*request that sponsors involve authors at an early stage in publication planning and should resist attempts to do detailed work on a publication before the authors have been confirmed and the content of the proposed publication discussed with them*'.

Writers should 'request that sponsors involve authors at an early stage in publication planning'

EMWA guidelines

Both the GPP and EMWA guidelines discourage the practice of sending only a completed (and near-final) draft to authors for approval rather than involving them in planning the publication from the outset. The EMWA guidelines state that '*Medical writers should discuss and agree the content of a publication or presentation with the named author(s) before preparing a detailed draft. Getting the named author(s) to approve a publication outline and key messages is usually the best way to achieve this*.' All named authors should have the opportunity to comment on an outline. For a paper reporting a clinical trial this might set out the key messages and indicate which tables will be included. For a literature review, an outline should identify:

- the topic of interest
- how the question will be defined
- the scope of the review (exclusion and inclusion criteria for articles)
- methods for the review (e.g. which databases will be searched).

An outline is supposed to be a discussion document, and should not resemble a complete paper. I have seen some which ran to a dozen pages and were really first drafts except that information was presented as bullet points rather than complete sentences and paragraphs.

An outline is supposed to be a discussion document, and should not resemble a complete paper

The ICMJE authorship criteria were broadened in 2001 by the inclusion of data acquisition as an activity which, along with developing the manuscript, qualified for authorship. This meant that, in theory, any investigator who recruited a single patient or took a single measurement could qualify for authorship so long as they reviewed the paper critically and approved the final version. In the previous version of the criteria, only those who had contributed to the design of the study or the analysis or interpretation of the data could qualify.

Developing an authorship strategy

This broadening of the criteria made it all the more important for sponsors to set out a clear authorship strategy and communicate this to all investigators. It is often not possible to identify everyone who will qualify as an author at the start of a trial, but it is always possible to agree on how this will be decided. For example, the authors might be the principal investigator, or a senior investigator from each centre, plus the highest recruiters (e.g. the top three), plus the statistician.

Establishing a core writing group at the start of the study can be helpful. This will usually comprise those responsible for the study protocol (i.e. the principal investigator(s), medical manager and statistician) who can be joined, when the study is complete, by others who have made a substantial contribution to the study and the publication.

Establishing a core writing group at the start of the study can be helpful

Access to data

Named authors and medical writers need access to the findings, usually in the form of a study report, in order to prepare and/or critique a publication. The EMWA guidelines suggest that medical writers should also have access to the protocol for details of the trial methods and to ensure that all outcomes are responsibly reported. Primary and secondary outcomes, and planned versus

post-hoc analyses should be clearly distinguished, and outcomes should not be selectively reported. Many journals now require authors to state that they had access to the underlying data. A few journals also require a copy of the study protocol, which is made available to reviewers.

Order of authors

The ICMJE criteria simply (and, to my mind, rather unhelpfully) state: "*The order of authorship on the byline should be a joint decision of the co-authors*". Similarly, the WAME policy statement on authorship says: "*The authors themselves should decide the order in which authors are listed in an article. No one else knows as well as they do their respective contributions and the agreements they have made among themselves. Many different criteria are used to decide order of authorship. Among these are relative contributions to the work and, in situations where all authors have contributed equally, alphabetical or random order*."

A notable exception to the lack of guidelines in most journals is found in a guide to writing for the so-called 'green journal', *Obstetrics & Gynecology* (Figure 4).[16]

Where are we now?

There has been support from many journal editors for the GPP and EMWA guidelines (which are featured in the instructions to authors for several journals, including the *BMJ*, and all titles published by BioMed Central and the Public Library of Science). The GPP guidelines were also endorsed by a UK House of Commons select committee on the pharmaceutical industry. The guidelines have also been influential in the development of publication guidelines by the Pharmaceutical Research and Manufacturers of America (PhRMA).

'Medical writers can be legitimate contributors'

WAME Policy Statement

Scientific authorship and its associated problems has become a topic for academic research[17] as well as of recent policy statements from the Council of Science Editors and the WAME.

From the medical writer's viewpoint, considerable progress has been made, from a time in which many journal editors condemned the profession to a point at which WAME could state '*medical writers can be legitimate contributors*' and professional writers are even mentioned in *The Lancet*'s instructions to authors.

What next?

Calls for increased transparency around the preparation of publications and the involvement of commercial sponsors seem set to increase. The influential members of the ICMJE now recommend that all journals should adopt the contributorship system (although most specialty journals still do not do so).

Methods for reporting clinical trials are evolving, with the growth of databanks and online reports.[18] Until now, the authorship of trial reports prepared for regulatory authorities has received little attention or discussion, but this may change if study protocols are published more widely or electronic reports replace traditional journal articles as the primary mode for communicating research findings. A recent study highlighted the fact that company personnel who develop protocols are rarely acknowledged in publications.[13] Contract research companies and pharmaceutical companies should probably start thinking about their policies on this.

In the medium term, articles in peer-reviewed journals will continue to play a central role in medical communications. As such, writers, communications companies and commercial sponsors need to review their policies to ensure they are compliant with current journal policies. It would also be helpful if academic institutions took a lead and issued practical guidance on authorship since misconduct is not restricted to industry-funded projects. Real progress could be made and much dispute and wasted time avoided if industry and academia could agree on universal authorship criteria and the best methods for acknowledging contributions to publications.

Disputes about the order of listing authors are likely to continue, since there are virtually no published guidelines on this. At present, the best policy is to agree a writing group and establish authorship criteria, including the proposed order of listing, as early as possible in the life of a trial.

Confusion remains about the precise distinctions between authors, contributors and acknowledgees, but it is clear that writers' contributions must be documented

"The first author should be the person who contributed most to the work and wrote most of the manuscript. Other names usually follow in order of their relative contributions, although some prefer to list the senior laboratory or departmental leader last. This is permissible only if that individual fulfilled the criteria of authorship applicable to all."

Fig. 4. Suggestions on the order of authors in *Obstetrics & Gynecology*.[16]

somewhere in all publications they help to develop. Once they are properly acknowledged, medical writers cease to be ghosts. Many journals are demanding increasing transparency for all aspects of publications (including funding, access to data and the role of sponsors), so writers, communications agencies and healthcare companies need to keep abreast of these developments.

The world of peer-reviewed publications may seem like a jungle, full of predatory creatures and lurking dangers. Medical writers need to balance the needs and expectations of their customers with those of the investigators/authors and journal editors. Various recent publications, in particular the GPP guidelines and the EMWA guidelines on the role of medical writers, can help to achieve the necessary balance.

> *"Medical writers are not a fifth column but are working in a fast moving modern environment to help disseminate scientific information"*[20]

Writing in the foreword to the latest edition of the *AMA Manual of Style*, the editor of *JAMA*, Cathy DeAngelis notes: "*I never cease to be amazed by the general inability of physicians, other health professionals, and scientists to communicate through the written word*."[19] This, perhaps, suggests that professional writers have a useful role in improving medical publications. Earlier this year (2007) the *BMJ* published a personal view that concluded "*Medical writers are not a fifth column but are working in a fast moving modern environment to help disseminate scientific information. They are here to stay, and their work needs to be embraced and acknowledged to increase the transparency of public information*."[20] Where the general journals (such as the members of the ICMJE) lead, the smaller, specialty journals tend to follow, and a recent editorial in a dermatology journal was headed '*Transparency is the key to the relationship between biomedical journals and medical writers*'.[21] Writers and the companies hiring or employing them need to embrace this simple message and also work with journal editors to educate them about what professional writers can contribute to publications and to agree best practice for their involvement.

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Pharma Marketing ROI

A KeywordPharma **Conference Insights** by **Dr Barrie G James** Published January 2007

ThePharmYard product code kwp014 ISBN-13: 978-1-905676-13-2

An in-depth report from the eyeforpharma 6th Annual European Pharmaceutical Congress, held in Amsterdam, 23–24 October 2006.

Executive Summary

Caught in a tightening vice between declining new product introductions and accelerating patent erosion, the pharmaceutical industry has been cutting back spending across the board to improve profits. Conversely, marketing spend is at an all-time high and is now the single largest pharmaceutical company business expenditure. Inevitably, this has triggered a growing management emphasis on accountability and on value for money for its marketing investments. Pharma marketers' response has been to explore and implement approaches that improve return on investment (ROI).

The 6th Annual European Pharmaceutical Conference, Pharma Marketing ROI, held in Amsterdam on 23–24 October 2006, discussed the challenges that the industry faces and its implications for a healthy financial future, together with some of the measures and practices that could deliver increased ROI in pharma marketing.

The conference raised two burning issues: first, do pharmaceutical companies possess a solid bedrock of marketing expertise in terms of best practice processes and procedures? If not, the expectations of enhanced marketing ROI may not be realised. Second, how many companies have processes in place that can identify, track and allocate marketing expenses? Without these systems it is impossible to calculate an accurate ROI. The evidence presented suggests that very few companies are well positioned in this respect.

Addressing these issues will be critical for the future. It has been projected that global industry growth will continue its unbroken decline from 2000 and will slow to 5–6% growth in 2005/6, down from 6–7% in 2004/5. Reduced growth inevitably increases the level of competition throughout the industry, which will only add to the pressures on those companies that are unable to maximise their marketing ROI.

Contents

About the author

Dr Barrie G James is internationally recognised as a leading-edge pharmaceutical thinker, for his consulting in pharma strategy, futures, ethics and evidence-based marketing. He manages Pharma Strategy Consulting in Huntingdon, UK, which specialises in creative and pragmatic solutions to fundamental strategic, ethical and marketing problems in the pharma industry.

Earlier in his career, Barrie held executive positions at Ciba-Geigy, Merck & Co., Syntex, Biogen and Schering-Plough in strategic planning, marketing, operating management and business development.

His books and reports on the pharma industry have become standard industry references and his work has been cited in *Business Week*, the *Economist* and the *Financial Times*. His latest publications are *The Little Black Book of Pharma Marketing* and *PharmVision 2015: A Short History of the Future*.

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